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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,712	COLLAND ET AL.	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12 and 14-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 10-12, and 15-27, drawn to the special technical feature of a method for treating a patient with cancer in which TCF/β catenin signaling is deregulated comprising administering a therapeutic composition to said patient comprising an inhibitor of the expressed protein or peptide therefrom, of a TCF target gene whose expression is regulated by a TCF/β catenin complex.

Group II, claim(s) 6-12 and 15-27, drawn to the special technical feature of a method for treating a patient with cancer in which TCF/β catenin signaling is deregulated comprising administering a therapeutic composition to said patient comprising an inhibitor of the mRNA transcript of a target gene whose expression is regulated by a TCF/β catenin complex.

Group III, claim(s) 14-27, drawn to the special technical feature of a method for diagnosing a patient with cancer in which TCF/β catenin signaling is deregulated

wherein the diagnosis is by histological analysis of a tissue specimen using (i) a specific antibody directed against a target gene product and/or (i) *in situ* hybridization analysis of a TCF/β catenin target gene expression level in tissue specimens using specific RNA probes directed against the TCF/β catenin target gene sequence.

Group IV, claim(s) 28-32, 36-48, 51, and 53 drawn to the special technical feature of an inhibitor compound directed against the expressed proteins, or peptides derived therefrom, of a TCF target gene the expression of which is regulated by a TCF/β catenin complex; and a therapeutic composition for the treatment of cancer in which the TCF/β catenin signaling is deregulated comprising a suitable excipient, carrier, and/or diluent, and one or more of the inhibitor compounds of claim 28.

Group V, claim(s) 33-48, 51, and 53 drawn to the special technical feature of an inhibitor compound directed against the transcription product (mRNA) of a TCF target gene the expression of which is regulated by TCF/β catenin complex; a therapeutic composition for the treatment of cancer in which the TCF/β catenin signaling is deregulated comprising a suitable excipient, carrier, and/or diluent, and one or more of the inhibitor compounds of claim 33.

Group VI, claim(s) 49, 50, 52, and 53, drawn to the special technical feature of a diagnostic agent for diagnosing cancers in which TCF/β catenin signaling is deregulated.

Group VII, claim(s) 54 and 55, drawn to the special technical feature of a method for the development of therapeutic inhibitor compounds as claimed in claim 28 or 33.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-VII appears to be an agent that binds the product of a target gene whose expression is regulated by a TCF/β catenin complex.

However, said technical feature does not constitute a special technical feature in view of Naor et al (Advances in Cancer Research, 1997, 71:241-319). Naor et al teach antibodies that bind CD44, used for treating cancer and diagnosing cancer (p. 290-291, section B; entire section XII, A-J; p. 306, last paragraph).

As evidenced by Zhang et al (Molecular and Cellular Biology, 2006, 26:2055-2064), CD44 is a β catenin target gene (p. 2062, col. 1, 2nd paragraph).

Therefore, the technical feature linking the inventions of Groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups I-VII are not so linked by the same or a corresponding special technical feature as to form a single general incentive concept and restriction for examination purposes as indicated is proper.

SPECIES ELECTIONS

Species Election for Group I

A. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of inhibitor are as follows: **antibody (claims 2-4) or small molecules that interferes with the biological activity of the protein expressed by the target gene (claim 5).**

The following claim(s) are generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each inhibitor is structurally and functionally distinct.

If Applicants elect "antibody" in A above, Applicants must elect a species in B below:

B. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of peptide are as follows: **Elect ONE peptide from claim 3.**

The following claim(s) are generic: claim 3.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: Each peptide is structurally and functionally distinct and requires distinct antibodies to bind them.

C. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of target gene/expressed protein are as follows: **Elect ONE target gene listed in claims 15-27. If the expressed protein in claims 22-27 correspond to an elected target gene in the claims, Applicants must identify the corresponding expressed protein claim.**

The following claim(s) are generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene/protein is structurally and functionally distinct.

D. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of disease being treated are as follows: **FAP (claim 10), colorectal cancer (claim 11), or melanoma (claim 12).**

The following claim(s) are generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each disease is etiologically and functionally distinct.

Species Election for Group II

E. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of inhibitor are as follows: **antisense molecule (claim 7) or double stranded RNA interference (claim 8).**

The following claim(s) are generic: claim 6.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each inhibitor is structurally and functionally distinct.

F. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of disease being treated are as follows: **FAP (claim 10), colorectal cancer (claim 11), or melanoma (claim 12).**

The following claim(s) are generic: claim 6.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each disease is etiologically and functionally distinct.

G. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of target gene/expressed protein are as follows: **Elect ONE target gene listed in claims 15-27. If the expressed protein in claims 22-27 correspond to an elected target gene in the claims, Applicants must identify the corresponding expressed protein claim.**

The following claim(s) are generic: claim 6.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene/protein is structurally and functionally distinct.

Species Election for Group III

H. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of target gene/expressed protein are as follows: **Elect ONE target gene listed in claims 15-27. If the expressed protein in claims 22-27 correspond to an elected target gene in the claims, Applicants must identify the corresponding expressed protein claim.**

The following claim(s) are generic: claim 14.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene/protein is structurally and functionally distinct.

Species Election for Group IV

I. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of inhibitor are as follows: **antibody (claims 29-31) or small molecules that interferes with the biological activity of the protein expressed by the target gene (claim 32).**

The following claim(s) are generic: claim 28.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each inhibitor is structurally and functionally distinct.

If Applicants elect "antibody" in I above, Applicants must elect a species in J below:

J. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of peptide are as follows: **Elect ONE peptide from claim 30.**

The following claim(s) are generic: claim 30.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each peptide is structurally and functionally distinct and requires distinct antibodies to bind them.

K. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of target gene/expressed protein are as follows: **Elect ONE target gene listed in claims 36-48. If the expressed protein in claims 43-48 corresponds**

to an elected target gene in the claims, Applicants must identify the corresponding expressed protein claim.

The following claim(s) are generic: claim 28.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene/protein is structurally and functionally distinct.

Species Election for Group V

L. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of inhibitor are as follows: **antisense molecule (claim 34) or double stranded RNA interference (claim 35).**

The following claim(s) are generic: claim 33.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each inhibitor is structurally and functionally distinct.

M. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of target gene/expressed protein are as follows: **Elect ONE target gene listed in claims 36-48. If the expressed protein in claims 43-48 corresponds to an elected target gene in the claims, Applicants must identify the corresponding expressed protein claim.**

The following claim(s) are generic: claim 33.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene/protein is structurally and functionally distinct.

Species Election for Group VI

N. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of diagnostic agent are as follows: **antibody (claim 50) or RNA probe (claim 50).**

The following claim(s) are generic: claim 49.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: Each agent is structurally and functionally distinct and directed against structurally and functionally distinct molecules.

Species Election for Group VII

O. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of target gene are as follows: **Elect ONE target gene listed in claim 55.**

The following claim(s) are generic: claim 54.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene is structurally and functionally distinct.

P. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of inhibitor compound are as follows: **inhibits protein (as recited in claim 28) or inhibits mRNA (as recited in claim 33).**

The following claim(s) are generic: claim 54.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each agent is structurally and functionally distinct and directed against structurally and functionally distinct molecules.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard, Ph.D./
Examiner, Art Unit 1642